

## **DETAILED ACTION**

### ***Status of Objections and Rejections***

1. Amendment filed in the paper of March 3, 2008 is entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2 are pending.

Claims 3-30 are cancelled.

Claims 1-2 are examined on merits in this Office action.

Objections to the specification have been withdrawn in light of amendments to the specification filed in the paper of March 3, 2008.

Objection to the drawings is withdrawn in light of amendment to the specification filed in the paper of March 3, 2008.

Rejection of claims 1-2 under 35 U.S.C. 101 for claiming non-statutory subject matter is withdrawn in light of claim amendments filed in the paper of March 3, 2008.

Rejections of claims 1-2 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph are withdrawn in light of claim amendments filed in the paper of March 3, 2008.

Rejection of claims 1-2 under 35 U.S.C. 112, 1<sup>st</sup> paragraph (written description) is withdrawn in light claim amendments filed in the paper of March 3, 2008.

### ***Claim Objections***

2. Claim 1 is objected to because of the following informalities:

Claim 1 is objected for the recitation "such that " in line 6, because the recitation does not read properly. It is suggested to change the recitation "such that" to --and wherein--.

***Election/Restrictions***

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

4. Claims 1-2 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant with increased growth rate and large inflorescence comprising transformation of a plant with a nucleic acid encoding a plant class-2 non-symbiotic haemoglobin protein as defined in SEQ ID NO: 4, does not reasonably provide enablement for increasing expression of a nucleic acid sequence encoding said class-2 non-symbiotic haemoglobin protein by a method other than transforming a plant with said nucleic acid sequence. The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art which it pertains, or which it is most nearly connected, to make and/or

use the invention commensurate in scope with the claims for the reasons of record stated in the Office action mailed on October 1, 2007.

It is noted that Applicant did not address this issue in the response filed March 3, 2008.

It is, therefore, maintained that the instant specification fails to provide guidance on a method of altering plant characteristics comprising increasing expression of a nucleic acid sequence encoding plant class-2 non-symbiotic haemoglobin (SEQ ID NO: 4) in any manner other than transforming a plant with a nucleic acid sequence encoding a plant class-2 non-symbiotic haemoglobin protein of SEQ ID NO: 4. The specification does not provide guidance on co-factors, or positive regulators of class-2 non-symbiotic haemoglobin for example that makes the class-2 non-symbiotic haemoglobin gene to overexpress to produce a plant with said altered characteristic. The specification provides no guidance on up-stream regulatory factors, for example, that may be necessary in stimulating the overexpression of endogenous class-2 non-symbiotic haemoglobin (SEQ ID NO: 4).

In the absence guidance, it is therefore maintained that undue experimentation would have been required by a skilled artisan at the time the claimed invention was made to determine how a plant with altered characteristics could have been produced by a method that comprises increasing the expression of a nucleic acid sequence encoding a plant class-2 non-symbiotic haemoglobin without transforming the plant with a nucleic acid sequence encoding a plant class-2 non-symbiotic haemoglobin (SEQ ID NO: 4).

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention commensurate in scope with the claims.

***Claim Rejections - 35 USC § 102***

5. Claims 1-2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (EP 1033405 A2, Published June 9, 2000) taken with the evidence of Trevaskis et al. (PNAS, 94:12230-12230, 1997, also see GenBank sequence accession No. U94999 cited in the reference) for the reasons of record stated in the Office action mailed October 1, 2008. Applicant traverses the rejection in the paper filed on March 3, 2008.

Applicant argues that Alexandrov et al. do not disclose an expression cassette where the nucleic acid molecule encoding SEQ ID NO: 44959 is combined with a promoter for increasing expression of a class-2 non-symbiotic haemoglobin. Applicant further argues that the reference does not disclose altered plant growth characteristics (response, pg 8, lines 8-15).

Applicant's arguments have been fully considered but were deemed to be unpersuasive.

It is maintained that Alexandrov et al. disclose a method of producing a transgenic plant cell comprising transformation of said plant cell with a vector comprising an expression cassette (same as gene construct) which comprises a nucleic

acid sequence encoding the polypeptide of SEQ ID NO: 44959 which has 100% sequence identity to instant SEQ ID NO: 4. The reference further discloses that the vector comprising said nucleic acid sequence is operably linked to a promoter (pages 22-23, and 327-329). The reference further discloses regenerating a transgenic plant from said transformed plant cell. The reference also discloses transgenic plants over-expressing the nucleic acid sequence encoding the polypeptide (SEQ ID NO: 44959) disclosed in the reference. See in particular, claims 1-34, pages 327- 335, 341-343 and SEQ ID NO: 44959. It is also maintained that the sequence (SEQ ID NO: 44959) disclosed by Alexandrov et al. has 100% sequence identity to *Arabidopsis* class-2 haemoglobin as evidenced by Trevaskis et al.

It is further maintained that although Alexandrov et al. do not explicitly disclose the properties of increased yield, increased biomass, increased floral architecture (encompassed by altered architecture) or increased cell division (encompassed by altered cell division), such properties would be inherent to the method disclosed in the reference which comprises expression of a polynucleotide sequence encoding SEQ ID NO: 44959 disclosed in the reference. Accordingly, Alexandrov et al. anticipated the claimed invention.

See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343,1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and

thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently "rich in glucosinolates").

Also see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

Accordingly, Alexandrov et al. anticipated the claimed invention.

### ***Conclusions***

6. Claims 1-2 remain rejected.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is set to expire within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1638

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phuong T. Bui/

Primary Examiner, Art Unit 1638